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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/450,511	11/30/1999	KAORU ARAI	P18214	7711

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EXAMINER

MAYES, MELVIN C

ART UNIT

PAPER NUMBER

1734

DATE MAILED: 02/10/2003

1. 9

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/450,511	ARAI ET AL.
	Examiner	Art Unit
	Melvin Curtis Mayes	1734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 11 October 2002.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-4, 6, 7, 9, 10 and 12-20 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4, 6, 7, 9, 10 and 12-20 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

*Claim Objections*

(1)

Applicant is advised that should claim 7 be found allowable, claim 13 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

*Claim Rejections - 35 USC § 103*

(2)

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(3)

Claims 1-4, 6, 7, 9 and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. 5,645,596 in view of Ogawa et al., Saita et al. 5,128,169, Shimp et al. and “Modern Ceramic Engineering.”

Kim et al. discloses a method of making a ceramic vertebrae prosthesis comprising: providing a dried dense material to correspond to the center portion, providing a dried porous material to correspond to the circumferential portion; adhering the dried dense material to the dried porous material by an apatite slurry; and heating the assembly. The ceramic is preferably a calcium phosphate ceramic and is advantageously calcium phosphate compound of Ca/P ratio of

1.0 to 2.0 such as hydroxyapatite and the porous portion is made to have a porosity of 20-55%.

The hydroxyapatite is made by a wet process using phosphate salt and calcium salt. Kim et al. disclose heating hydroxyapatite at 1000-1200°C to obtain a final product (col. 4, lines 18-38, 50-52, col. 5, lines 1-6 and 13-26). Kim et al. disclose that hydroxyapatite slurry can be prepared by a wet composition process using a phosphate salt and calcium salt but does not specifically disclose that the apatite slurry used to adhere the dried materials is synthesized by merely adding a phosphoric compound to a calcium compound slurry or is the same calcium phosphate compound as that of the dense and porous material.

Ogawa et al. teach that hydroxyapatite can be synthesized by various known methods including a wet method in which phosphoric acid or a water-soluble phosphate salt is reacted with a water-soluble calcium compound in an aqueous solution and a dry method in which phosphoric acid compound is reacted with a calcium compound under high temperatures. Ogawa et al. teach making a hydroxyapatite slurry by dropwise adding a phosphoric acid solution to a calcium hydroxide slurry (col. 3, lines 31-52, col. 6, lines 32-40).

Saita et al. teach that for forming a hydroxyapatite coating onto a substrate, hydroxyapatite prepared by a conventional method, such as wet process or dry process, and teaches that the wet process is preferable because a product having fine particle size can easily be obtained and the product of the wet process is preferably used without drying after filtering and washing with water because undesirable production of agglomerates is inhibited. Saita et al. further teach that the particle size of the primary flocculated particles of hydroxyapatite prepared by the wet process is 0.1 to 1  $\mu\text{m}$  when measured by a sedimentation method (col. 2, lines 35-45).

Shimp et al. teach that binders may interfere with the sintering process of hydroxyapatite, even if organic binders which leave no mineral residue upon firing are used (col. 1, lines 40-43).

Modern Ceramic Engineering teaches that sintering of ceramic comprises stages including an initial stage of particle rearrangement and neck formation at the contact point between particles, an intermediate stage of neck growth and grain growth in which a particle begins to grow while the adjacent particle is consumed, and a final stage of much grain growth with porosity elimination (pgs. 520-522).

It would have been obvious to one of ordinary skill in the art to have adhered the dried dense material and dried porous material of hydroxyapatite by an apatite (hydroxyapatite) slurry prior to heating (sintering) in the method of Kim et al. using a slurry prepared by adding a phosphoric compound to a calcium compound slurry, as Ogawa et al. teach that the wet method (in which phosphoric acid or a water-soluble phosphate salt is reacted with a water-soluble calcium compound in an aqueous solution) and the dry method are known methods of making a hydroxyapatite slurry, and Saita et al. teach that for forming a hydroxyapatite coating onto a substrate, hydroxyapatite prepared by a wet process is preferable because a product having fine particle size can easily be obtained. Using a slurry of hydroxyapatite particles prepared by a wet process for coating one or both of the dried materials of hydroxyapatite for adhering the materials would have been obvious to one of ordinary skill in the art as preferable for easily providing fine particle size needed for providing a coating, as taught by Saita et al. Using a hydroxyapatite slurry prepared by the wet method would have been obvious to one of ordinary skill in the art because preparing hydroxyapatite slurry by the wet method is well known in the art, as taught by Kim et al., Ogawa et al., and Saita et al. Using hydroxyapatite slurry to adhere

hydroxyapatite parts would have been obvious to one of ordinary skill in the art to provide the same material throughout the prosthesis made of the bonded parts.

Using a hydroxyapatite slurry prepared without drying the hydroxyapatite after forming by the wet process, and thus synthesized by merely adding a phosphoric compound to a calcium compound slurry as claimed in Claim 1, would have been obvious to one of ordinary skill in the art as Saita et al. to inhibit the undesirable production of agglomerates. Further, using a hydroxyapatite slurry prepared in the absence of organic components, as claimed in Claim 19, such as organic binder, for coating one or both of the dried materials for adhering the materials would have been obvious to one of ordinary skill in the art, as taught by Shimp et al. to prevent interference with the sintering process of hydroxyapatite.

By heating at 1000-1200°C to obtain a final product, as disclosed by Kim et al., the particles of the slurry fuse and grow during the sintering of the dried dense material and dried porous material, as Modern Ceramic Engineering teaches that sintering of ceramic comprises stages including an initial stage of particle rearrangement and neck formation at the contact point between particles, an intermediate stage of neck growth (i.e. fusing of particles) and grain growth, in which a particle begins to grow while the adjacent particle is consumed, and a final stage of much grain growth with porosity elimination.

It would have been obvious to one of ordinary skill in the art to have prepared the slurry to have primary particles of average grain size in the range of 0.1 to 1  $\mu\text{m}$ , and thus including the range of 0.05 to 0.5  $\mu\text{m}$  as claimed in Claim 10, as Saita et al. teach that the particle size of the primary flocculated particles of hydroxyapatite prepared by the wet process is 0.1 to 1  $\mu\text{m}$  when measured by a sedimentation method.

In the event any differences can be shown for the product of the product-by-process claims 17 and 18, as opposed to the product taught by the combination of Kim et al., Ogawa et al., Saita et al., Shimp et al. and “Modern Ceramic Engineering,” such differences would have been obvious to one of ordinary skill in the art as a routine modification of the product in the absence of a showing of unexpected results; see also *In re Thorpe*, 227 USPQ 964 (CAFC 1985).

When the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or 103 of the statute is appropriate. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. A lesser burden of proof is required to make out a case of *prima facie* obviousness for product-by-process claims because of their particular nature than when a product is claimed in the conventional fashion. *In re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972); *In re Fessmann*, 180 USPQ 324 (CCPA 1974).

(4)

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of JP 2-225382.

JP '382 teaches that apatite of average particle size of 0.1 to 15 microns is suitable for applying between apatite products for bonding the products. JP '382 also teaches that the apatite is provided such that it is 5 to 40 wt% of an aqueous solution used for a bonding material (Abstract).

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by providing the amount of apatite in the bonding slurry in an amount in the range of 5 to 40wt%, and thus encompassing the range of 0.1 to 20vol% as claimed in Claim 9, as taught by JP '382 as the amount of apatite in an aqueous solution for a bonding material.

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by providing particles of average grain size in the range of 0.1 to 15 microns in the slurry, and thus 0.05 to 0.5 microns as claimed in Claim 10, as taught by JP '382 as the average particle size of apatite suitable for applying between apatite products for bonding the products.

*Response to Arguments*

(5)

Applicant's arguments filed October 11, 2002 have been fully considered but they are not persuasive.

Applicant argues that Claim 1 claims that the ceramic bodies and bonding ceramic are formed of a phosphoric compound and the bonding ceramic is the same material as the ceramic body. Kim is silent as to whether the ceramic material of the slurry is the same material as that of the dried dense material and dried porous material. Applicant argues that the slurry of Ogawa contains two or more ceramic materials and does not teach nor suggest that each of the two ceramic bodies is formed of a phosphoric compound and that the bonding ceramic is formed of the same material as each body and argues that Ogawa is directed to the formation of porous

ceramic materials from slurries. Applicant argues that Saita is not directed to interposing a slurry between two ceramic bodies and argues that Shimp does not provide any motivation for modifying the process of Kim. Applicant argues that the Examiner has not addressed why one skilled in the art would modify the slurry of Kim based on the other documents.

(6)

Applicant's arguments have been considered but are not convincing. The disclosure of Kim et al. suggests adhering a dried dense ceramic part to a dried porous ceramic part using an apatite slurry and heating to bond the parts together. Because hydroxyapatite is an apatite and Kim et al. suggests that a calcium phosphate ceramic compound such as hydroxyapatite which has a Ca/P ratio of 1.0 to 2.0 is preferable for the ceramic parts, the Examiner's position is that the disclosure of Kim et al. would have led one of ordinary skill in the art to adhere dried ceramic parts of hydroxyapatite with a hydroxyapatite slurry.

Further Kim et al. disclose using an apatite slurry. In Example 1 of the reference, a hydroxyapatite "slurry" is prepared by a wet composition process and according to the reference, this involves using phosphate salt and calcium salt. This suggests that the apatite "slurry" for adhering the parts is also made the same way, thus suggesting that the slurry is "synthesized by merely adding a phosphoric compound to a calcium compound slurry," as claimed in Claim 1, and contains "no organic components therein for preventing elution of organic components into a human body," as claimed in Claim 19. The cited references Ogawa et al and Saita et al. reinforce the disclosure of Kim et al. of how hydroxyapatite is synthesized by the wet process and how a hydroxyapatite slurry is formed, Saita et al. being particularly important because it suggests that to use hydroxyapatite for coating onto a substrate (which is how the apatite slurry of Kim et al.

needs to be used between the dried parts) hydroxyapatite prepared by the conventional wet process is used as is without any other processing such as drying after filtering and washing with water.

With respect to no organic components in the slurry used for adhering, because apatite slurry is made by a wet composition process using phosphate salt and calcium salt, there is thus no organic components in the slurry. Shimp was cited because the reference suggests that binders may interfere with the sintering process of hydroxyapatite, even if organic binders which leave no mineral residue upon firing are used. This is further suggestion not to include organic in the slurry, nor in the parts to be bonded. There is no mention in Kim et al. of even using any kind of binder to make the dense and porous parts to be bonded. JP '382 teaches that apatite of average particle size of 0.1 to 15 microns is suitable for applying between apatite products for bonding the products, encompassing the range of Claim 10.

***Conclusion***

(7)

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

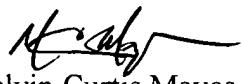
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

(8)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melvin Curtis Mayes whose telephone number is 703-308-1977. The examiner can normally be reached on Mon-Fri 7:30 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 703-308-3853. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

  
Melvin Curtis Mayes  
Primary Examiner  
Art Unit 1734

MCM  
February 6, 2003